PATENT

IN THE UNITED STATES PATENT AND TRADEMARK OFFICE

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Applicant:	HYON, Suong-Hyu et al.
Group Art Unit:	1711
Examiner:	BERMAN, Susan
Title:	ULTRA HIGH MOLECULAR WEIGHT POLYETHYLENE MOLDED ARTICLE FOR ARTIFICIAL JOINTS AND METHOD OF PREPARING THE SAME
Attorney Docket:	1736-000001/REC

APPENDIX A TO AMENDMENT FILED OCTOBER 18, 2005
COPY OF PREVIOUSLY SUBMITTED NEW CLAIMS AS FILED ON AUGUST 19, 2003

Dear Sir:

In response to the Office Action mailed May 18, 2005, attached is a copy of the claim listing containing new claims as filed with the August 19, 2003 reissue application, underlined in their entirety.

LISTING OF CLAIMS

1-11. (cancelled)

12. (new) An orthopedic preformed material for subsequent production of a medical implant with improved wear resistance, said preformed material is a polyethylene crosslinked by irradiation, and thermally treated according to the method selected from the group consisting of: annealing and remelting.

13. (new) The orthopedic preformed material of Claim 12, wherein said preformed material is crosslinked by gamma radiation at a dose from about 1 to about 5 MR.

14. (new) The orthopedic material of Claim 12, wherein said thermal treatment is remelting.

15. (new) The orthopedic material of Claim 12, wherein said thermal treatment is annealing.

16. (new) The orthopedic material of Claim 12, wherein said polyethylene is ultra high molecular weight polyethylene (UHMWPE).

17. (new) A medical implant having a bearing surface with improved wear resistance, said bearing surface comprising a solid polyethylene which has been previously crosslinked by irradiation and subsequently remelted.

18. (new) The medical implant of Claim 17, wherein said polyethylene is UHMWPE.

19. (new) The medical implant of Claim 18, wherein said polyethylene is crosslinked by gamma irradiation at a dose of at least about 1 MR.

20. (new) The medical implant of Claim 19, wherein said polyethylene is crosslinked by gamma radiation at a dose of from about 1 to about 5 MR.

21. (new) The medical implant of Claim 17, where said polyethylene is remelted at a temperature from the melting temperature of the irradiated polyethylene to about 80° C above the melting temperature of the irradiated polyethylene.

22. (new) The medical implant of Claim 17, wherein a layer of the crosslinked and remelted polyethylene is removed during processing into an implant.

23. (new) The medical implant of Claim 17, wherein said implant is a component for use in a joint prosthesis.

24. (new) The medical implant of Claim 23, wherein said component is a bearing component.

25. (new) The medical implant of Claim 24, wherein said joint prosthesis is selected from the group consisting of: hip and knee joint prostheses.

26. (new) The medical implant of Claim 25, wherein the implant is an acetabular cup.

27. (new) A medical implant having a bearing surface with improved wear resistance, said bearing surface comprising a solid polyethylene which has been previously crosslinked by irradiation and subsequently annealed.

28. (new) A medical implant of Claim 27, wherein said polyethylene has been previously crosslinked by irradiation and subsequently heated to a temperature between about 50° C below the melting point of said irradiated polyethylene and the melting temperature of said irradiated polyethylene.

29. (new) A medical implant of Claim 27, wherein said polyethylene has previously been crosslinked by irradiation and subsequently isothermally treated at a temperature of from about 100°C to about 130°C for a period of time from about 1 hour to about 20 hours.

30. (new) The medical implant of Claim 27, wherein said polyethylene is UHMWPE.

31. (new) The medical implant of Claim 27, wherein said polyethylene is crosslinked by gamma radiation of at least about 1MR.

32. (new) The medical implant of Claim 31, wherein said polyethylene is crosslinked by gamma radiation at a dose of from about 1 to about 5 MR.

33. (new) The medical implant of Claim 27, wherein a layer of the crosslinked and annealed polyethylene is removed during processing into an implant.

34. (new) The medical implant of Claim 27, wherein said implant is a component for use in a joint prosthesis.

35. (new) The medical implant of Claim 34, wherein said component is a load-bearing component.

36. (new) The medical implant of Claim 35, wherein said joint prosthesis is selected from the group consisting of: hip and knee joint prostheses.

37. (new) The medical implant of Claim 36, wherein the implant is an acetabular cup.

38. (new) A method for increasing the wear resistance of a preformed polyethylene comprising the steps of:

(a) crosslinking said polyethylene by irradiating it in a solid state; and

(b) subjecting the crosslinked polyethylene to thermal treatment which is selected from the group consisting of: annealing and remelting.

39. (new) The method of Claim 38, wherein said crosslinking is by gamma irradiation.

40. (new) The method of Claim 39, wherein the gamma irradiation is at a dose of at least about 1 MR.

41. (new) The method of Claim 40, wherein the gamma irradiation is at a dose of from about 1 to about 5 MR.

42. (new) The method of Claim 38, wherein said thermal treatment comprises annealing the crosslinked preformed polyethylene.

43. (new) The method of Claim 38, wherein said thermal treatment comprises heating said polyethylene to a temperature between about 50° C below the melting temperature of said irradiated preformed polymer and about the melting temperature of said irradiated preformed polyethylene.

44. (new) The method of Claim 38, wherein said thermal treatment comprises heating said polyethylene to a temperature of from about 100°C to about 130°C for a period of from about 1 hour to about 20 hours.

45. (new) The method of Claim 38, wherein said polyethylene is UHMWPE.

46. (new) A method for increasing the wear resistance of an orthopedic preformed polyethylene polymer, comprising the steps of:

(a) crosslinking the preformed polyethylene polymer by irradiating it in a solid state;

(b) subjecting the crosslinked preformed polymer to thermal treatment which is selected from the group consisting of: annealing and remelting; and

(c) removing the surface of the thermally treated crosslinked preformed polymer wherein said polymer is polyethylene.

47. (new) The method of Claim 46, wherein said polyethylene is UHMWPE.

48. (new) The method of Claim 46, wherein said polyethylene is crosslinked by gamma radiation at a dose of at least about 1 MR.

49. (new) The method of Claim 48, wherein said polyethylene is crosslinked by gamma radiation at a dose of from about 1 to about 5 MR.

50. (new) The method of Claim 46, wherein said polyethylene is remelted at a temperature from the melting temperature of the irradiated polyethylene to about 80° C above the melting temperature of said irradiated polyethylene.

51. (new) The method of Claim 46, wherein said polyethylene is heated to a temperature between about 50° C below the melting temperature of said irradiated preformed polyethylene below and the melting temperature of said irradiated preformed polyethylene.

52. (new) The method of Claim 46, wherein said thermal treatment comprises heating said polyethylene to a temperature of from about 100°C to about 130°C for a period of from about 1 hour to about 20 hours.

53. (new) A method for increasing the wear resistance of a preformed polymer, comprising the steps of:

(a) crosslinking said preformed polymer by irradiating it in its solid state; and

(b) remelting said crosslinked polymer, said polymer being polyethylene.

54. (new) The method of Claim 53, wherein said remelting temperature is between the melting temperature of the irradiated polymer to about 80° C above the melting temperature of said irradiated polymer.

55. (new) The method of Claim 53, wherein said preformed polymer is UHMWPE.

56. (new) The method of Claim 53, wherein the preformed polymer is crosslinked by gamma radiation at a dose of at least about 1 MR.

57. (new) The method of Claim 56, wherein the preformed polymer is crosslinked by gamma radiation at a dose of from about 1 to about 5 MR.

58. (new) A preformed polyethylene made according to a method comprising the steps of:

(a) crosslinking a starting polyethylene by irradiating it in a solid state to form a crosslinked polyethylene; and

(b) subjecting the crosslinked polyethylene to thermal treatment which is selected from the group consisting of: annealing and remelting;

wherein said preformed polyethylene has improved wear resistance over untreated polyethylene.

59. (new) The preformed polyethylene of Claim 58, wherein said crosslinking is by gamma irradiation.

60. (new) The preformed polyethylene of Claim 59, wherein said gamma irradiation is at a dose of from at least about 1 MR.

61. (new) The preformed polyethylene of Claim 60, wherein said gamma irradiation is at a dose of from about 1 to about 5 MR.

62. (new) The preformed polyethylene of Claim 58, wherein said thermal treatment comprises annealing said crosslinked polyethylene.

63. (new) The preformed polyethylene of Claim 58, wherein said thermal treatment comprises heating said crosslinked polyethylene to a temperature between about 50° C below the melting point of said irradiated polyethylene and the melting temperature of said irradiated polyethylene.

64. (new) The preformed polyethylene of Claim 58, whenever said thermal treatment comprises heating said polyethylene to a temperature of from about 100°C to about 130°C for a period of from about 1 hour to about 20 hours.

65. (new) The method of Claim 58, wherein said polyethylene is UHMWPE.

66. (new) A preformed polyethylene polymer made according to a method comprising the steps of:

(a) crosslinking a starting polyethylene polymer by irradiating in the presence of oxygen in a solid state to form a crosslinked polymer;

(b) subjecting said crosslinked polymer to thermal treatment selected from the group consisting of: annealing and remelting the crosslinked polymer; and

(c) removing the oxidized surface of the crosslinked polymer.

67. (new) The preformed polymer of Claim 66, wherein said polyethylene is UHMWPE.

68. (new) The preformed polymer of Claim 67, wherein said crosslinking is by gamma irradiation at a dose of at least about 1 MR.

69. (new) The preformed polymer of Claim 68, wherein said crosslinking is by gamma irradiation at a dose of from about 1 to about 5 MR.

70. (new) A preformed polymer made according to the method comprising the steps of:

(a) crosslinking a starting polymer by irradiating it in a solid state to form a crosslinked polymer; and

(b) remelting the crosslinked polymer, wherein said polymer is polyethylene.

71. (new) The preformed polymer of Claim 70, wherein the remelting temperature is between the melting temperature of the irradiated polymer to about 80° C above the melting temperature of the irradiated polymer.

72. (new) The preformed polymer of Claim 71, wherein said polymer is UHMWPE.

73. (new) The preformed polymer of Claim 70, wherein said crosslinking is by gamma irradiation at a dose of at least about 1 MR.

74. (new) The preformed polymer of Claim 73 wherein said crosslinking is by gamma irradiation at a dose of from about 1 to about 5 MR.

75. (new) An implantable load bearing component made by the process comprising the steps of:

(a) crosslinking a preformed polyethylene in its solid state;

(b) subjecting the crosslinked polyethylene to thermal treatment selected from the group consisting of: annealing and remelting; and

(c) fashioning the implantable bearing component from the crosslinked and thermally treated polyethylene.

76. (new) The implantable bearing component of Claim 75, wherein said polyethylene is UHMWPE.

77. (new) The implantable bearing component of Claim 75, wherein said polyethylene is crosslinked by gamma radiation at a dose of at least about 1 MR.

78. (new) The implantable bearing component of Claim 77, wherein said polyethylene is crosslinked by gamma radiation at a dose of from about 1 to about 5 MR.

79. (new) The implantable bearing component of Claim 75, wherein said thermal treatment is remelting.

80. (new) The implantable bearing component of Claim 75, wherein said polyethylene is heated to a température between about 50° C below the melting temperature of said irradiated preformed polyethylene below and the melting temperature of said irradiated preformed polyethylene.

81. (new) The implantable bearing component of Claim 75, wherein said polyethylene is isothermally treated at a temperature of from about 100°C to about 130°C for a period of from about 1 hour to about 20 hours.

82. (new) The implantable bearing component of Claim 75, wherein the implantable bearing component is for use in a joint prosthesis.

83. (new) The implantable bearing component of Claim 82, wherein said joint prosthesis is selected from the group consisting of: hip and knee joint prostheses.

84. (new) The implantable bearing component of Claim 83, wherein the implantable bearing component is an acetabular cup.

85. (new) A product made by the process comprising the steps of:

(a) crosslinking a preformed polymer by irradiating it in a solid state;

(b) subjecting the crosslinked polymer to thermal treatment selected from the group consisting of: annealing and remelting;

(c) removing the oxidized surface of the crosslinked polymer; and

(d) fashioning the product from the crosslinked and thermally treated polymer; wherein said polymer polyethylene.

86. (new) The product of Claim 85, wherein said polymer is UHMWPE.

87. (new) The product of Claim 85, wherein said polymer is crosslinked by gamma radiation at a dose of at least about 1 MR.

88. (new) The product of Claim 87, wherein said polymer is crosslinked by gamma radiation at a dose of from about 1 to about 5 MR.

89. (new) The product of Claim 85, wherein said thermal treatment is remelting.

90. (new) The product of Claim 85, wherein said thermal treatment comprises annealing said crosslinked polyethylene.

91. (new) The product of Claim 85, wherein said thermal treatment comprises heating said crosslinked polyethylene to a temperature between about 50° C below the melting point of said irradiated polyethylene and the melting temperature of said irradiated polyethylene.

92. (new) The product of Claim 85, wherein said thermal treatment comprises heating said polyethylene to a temperature from about 100°C to about 130°C for a period of from about 1 hour to about 20 hours.

93. (new) A medical implant having a bearing surface with improved wear resistance, said implant being made according to the process comprising the steps of:

(a) crosslinking a preformed polyethylene polymer by irradiating it in a solid state;

(b) subjecting the crosslinked polymer to thermal treatment selected from the group consisting of: annealing and remelting;

(c) removing the oxidized surface of the crosslinked polymer; and

(d) fashioning the implant from the crosslinked and thermally treated polymer.

94. (new) The medical implant of Claim 93, wherein said polymer is UHMWPE.

95. (new) The medical implant of Claim 94, wherein said polyethylene is crosslinked by gamma radiation at a dose of at least about 1 MR.

96. (new) The medical implant of Claim 95, wherein said polyethylene is crosslinked by gamma radiation at a dose of from about 1 to about 5 MR.

97. (new) The medical implant of Claim 93, wherein said thermal treatment is remelting.

98. (new) The medical implant of Claim 93, wherein said thermal treatment comprises annealing said crosslinked polyethylene.

99. (new) The medical implant of Claim 93, wherein said thermal treatment comprises heating said crosslinked polyethylene to a temperature between about 50° C below the melting point of said irradiated polyethylene and the melting temperature of said irradiated polyethylene.

100. (new) The medical implant of Claim 93, wherein said thermal treatment comprises heating said crosslinked polyethylene to a temperature of from about 100°C to about 130°C for a period of from about 1 hour to about 20 hours.

101. (new) The medical implant of Claim 93, wherein said medical implant is for use in a joint prosthesis.

102. (new) The medical implant of Claim 101, wherein said joint prosthesis is selected from the group consisting of: hip and knee joint prostheses.

103. (new) The medical implant of Claim 102, wherein the implant is an acetabular cup.

104. (new) A method for making an ultrahigh molecular weight polyethylene (UHMWPE) article, for subsequent processing to make a medical implant, comprising:

(a) irradiating a raw article comprising UHMWPE; and

(b) heating said article to a temperature of from about 50° C below the melting point of said article to about 80° C above said melting point.

105. (new) A method according to Claim 104, wherein said heating is at a temperature between about 50° C below the melting point of said article and said melting point.

106. (new) A method according to Claim 105, wherein said heating is at a temperature of from about 100°C to about 130°C for a period of from about 1 hour to about 20 hours.

107. (new) A method according to Claim 104, wherein said heating is at a temperature from about said melting point to about 80° C above said melting point.

108. (new) A method according to Claim 104, wherein said temperature is a compression deformable temperature.

109. (new) A method according to Claim 108, wherein pressure is applied during said heating step.

110. (new) A method according to Claim 109, wherein said article is isothermally heated after said pressure is applied.

111. (new) A method according to Claim 110, wherein said isothermal treatment comprises heating said article to a temperature of from about 100°C to about 130°C for a period of from about 1 hour to about 20 hours.

112. (new) An ultra high molecular weight polyethylene article made by the process of Claim 104.

113. (new) An article according to Claim 112 having a wear factor of less than about 9.6×10^{-7}.

114. (new) A method for making an ultra high molecular weight polyethylene (UHMWPE) article which is suitable for subsequent processing to make a medical implant, so as to improve the wear resistance properties of said article, comprising:

(a) irradiating a raw article comprising UHMWPE; and

(b) heating said article to a temperature of from about 50° C below the melting point of said article to about 80° C above said melting point.

115. (new) A method according to Claim 114, wherein said heating is at a temperature between about 50° C below the melting point of said article and said melting point.

116. (new) A method according to Claim 115, wherein said heating is at a temperature of from about 100°C to about 130°C for a period of from about 1 hour to about 20 hours.

117. (new) A method according to Claim 114, wherein said heating is at a temperature from about said melting point to about 80° C above said melting point.

118. (new) A method according to Claim 114, wherein said temperature is a compression deformable temperature.

119. (new) A method according to Claim 118, wherein pressure is applied during said heating step.

120. (new) An UHMWPE article made by a process of Claim 114.

121. (new) An UHMWPE article according to Claim 120 having a wear factor of less than about 9.6×10^{-7}.

122. (new) A method of making a component for an artificial joint comprising ultra high molecular weight polyethylene (UHMWPE), comprising:

(a) irradiating a raw article comprising UHMWPE;

(b) heating said article to a temperature of from about 50° C below the melting point of said article to about 80° C above said melting point; and

(c) processing said article to make said component.

123. (new) A method according to Claim 122, wherein said heating is at a temperature between about 50° C below the melting point of said article and said melting point.

124. (new) A method according to Claim 123, wherein said heating is at a temperature of from about 100°C to about 130°C for a period of from about 1 hour to about 20 hours.

125. (new) A method according to Claim 122, wherein said heating is at a temperature from about said melting point to about 80° C above said melting point.

126. (new) A method according to Claim 122, wherein said temperature is a compression deformable temperature.

127. (new) A method according to Claim 126, wherein pressure is applied during said heating step.

128. (new) A component for an artificial joint, wherein said component is made by a process according to Claim 122.

129. (new) A component for an artificial joint according to Claim 128, having a wear factor of less than about 9.6×10^{-7}.

130. (new) A method for making an ultrahigh molecular weight polyethylene (UHMWPE) article, for subsequent processing to make a medical implant, comprising:

(a) irradiating a raw article comprising UHMWPE; and

(b) heating said article to a temperature of from about 100° C to about 130° C for a period of at least about 1 hour.

131. (new) A method according to Claim 130, wherein said heating step comprises heating said article for from about 1 hour to about 20 hours.

132. (new) A method according to Claim 130, wherein said article is cooled at a constant rate after said heating step.

133. (new) A method according to Claim 132, wherein said cooling is at a rate of about 1° C/minute.

134. (new) A method according to Claim 130, additionally comprising a step, prior to said heating step, comprising applying pressure to said irradiated article at a deformation temperature.

135. (new) A method according to Claim 134, wherein said deformation temperature is between about 50° C below the melting point of said article and said melting point.

136. (new) A method according to Claim 134, wherein said deformation temperature is from about said melting point to about 80° C above said melting point.

137. (new) A UHMWPE article made by a process according to Claim 130.

138. (new) A UHMWPE article according to Claim 137 having a wear factor of less than about 9.6×10^{-7}.

139. (new) A method of making a component for an artificial joint comprising ultrahigh molecular weight polyethylene (UHMWPE), comprising:

(a) irradiating a raw article comprising UHMWPE; and

(b) heating said article to a temperature of from about 100° C to about 130° C for a period of at least about 1 hour; and

(c) processing said article to make said component.

140. (new) A method according to Claim 139, wherein said heating step comprises heating said article for from about 1 hour to about 20 hours.

141. (new) A method according to Claim 139, wherein said article is cooled at a constant rate after said heating step.

142. (new) A method according to Claim 141, wherein said cooling is at a rate of about 1° C/minute.

143. (new) A method according to Claim 139, additionally comprising a step, prior to said heating step, comprising applying pressure to said irradiated article at a deformation temperature.

144. (new) A method according to Claim 143, wherein said deformation temperature is between about 50° C below the melting point of said article and said melting point.

145. (new) A method according to Claim 143, wherein said deformation temperature is from about said melting point to about 80° C above said melting point.

146. (new) A component for a medical implant made by a process according to Claim 139.

147. (new) A component for a joint prosthetic device according to Claim 146.

148. (new) A component for an artificial joint according to Claim 146 having a wear factor of less than about 9.6×10^{-7}.